

## **Remarks**

Claims 1-5, 10-12 14-18, 20-30, 32, 35, 39, 41, 42, and 44-52 are pending in the above-referenced application and stand rejected. Claim 1, 18, 41, and 44 have been canceled, and claims 2-5, 10, 14-17, 20-26, 29, 30, 32, 39, 42, 46, and 49-51 have been amended. No new claims have been added. Applicant respectfully submits that no new matter is presented with these amendments. Applicant reserves the right to prosecute without prejudice in a future application subject matter amended from the claims by the Amendment submitted herewith. Applicant respectfully requests consideration of the amended claims presented herein and respectfully submits that the pending claims are now in condition for allowance.

### **I. Rejection under 35 U.S.C. § 112, first paragraph, for lack of written description.**

The Examiner has rejected claims 1-4, 10-11, 14-17, 20-30, 32, 35, 39, 42, 45, and 49-52 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner maintains that the Specification only provides written description support for “an endosomolytic polymer comprising monomers having ionizable functional moieties, which comprise proton acceptor sites, operably linked to one or more hydrolysable functional moieties selected from the group consisting of ortho-esters, hydrazones, and cis-acetonyls, wherein said polymer is capable of effecting the lysis of an endosome in response to a change in pH.” Applicant disagrees.

As described in the first paragraph of the “Summary of the Invention” on page 4 of the Specification, the invention includes in one embodiment an endosomolytic agent comprising a compound having at least one hydrolyzable functional moiety (lines 15-19), and in another embodiment a compound having at least one hydrozable functional moiety and at least one ionizable functional group (lines 21-25). Given the written description support for the first embodiment, which corresponds to claim 1, Applicant submits that the Specification does provide adequate written description support and that the rejection is in error.

However, in order to further prosecution, Applicant has canceled the claims drawn to endosomolytic agents without an ionizable functional group and amended the dependent claims

to depend from independent claim 5, which recites an endosomal lysing polymer with hydrolyzable and ionizable functional moieties. Applicant reserves the right to pursue claims drawn to the canceled subject matter in a future application. After entrance of the present Amendment, the rejection for lack of written description is rendered moot.

**II. Rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement.** The Examiner has rejected claims 1-12, 14-32, 35, 39, 41, 42, 45, and 46 under 35 U.S.C. § 112, first paragraph, for lack of enablement. As described above, all claims have been presently amended to include an endosomal lysing polymer including a hydrolyzable functional moiety and an ionizable moiety. Applicant submits that the amended claims are enabled by the specification for the full scope of the claims as indicated by the Examiner. Applicant, therefore, requests that the rejection be removed.

In the latest Office Action, the Examiner has indicated that claims 1-12, 14-32, 35, 39, 41, 42, 45, and 46 are rejected for lack of enablement. However, Applicant submits that some of these claims were amended in the last Response and should not have been rejected. In particular, claims 5, 12, 18, 41, and 44 should not have been rejected given the Examiner's exemplary list of enabled claims in the last Office Action. Applicant believes this error was just an oversight when the Office Action was drafted, but if this rejection is not removed, Applicant requests clarification on this point.

**III. Rejection under 35 U.S.C. § 103, as being unpatentable over Pack *et al.* (US 2001/0006817) taken with Thorpe (U.S. Patent 5,762,918).** Claims 1-12, 14-32, 35, 39, 41, 42, and 44-52 stand rejected under 35 U.S.C. § 103, as being unpatentable over Pack *et al.* (US 2001/0006817) taken with Thorpe (U.S. Patent 5,762,918). In order to remove US 2001/0006817 from consideration by the Examiner as not having been invented by another, Applicant has submitted with the last Response, filed December 2, 2003, a Declaration under 37 C.F.R. § 1.132 by Robert S. Langer stating that the claimed invention was not invented by another. Therefore, this reference is not available as prior art under 35 U.S.C. § 102(e).

The Examiner in response to the Declaration maintains that the Declaration is not persuasive for the removal of the Pack *et al.* reference because there is evidence of record to

indicate that the inventors of the Pack *et al.* reference are also inventors of the claimed invention. Pack, Putnam, and Langer are the inventors on the Pack *et al.* reference, and Putnam and Langer are inventors on the present application. Pack did not contribute to the conception of the claimed invention in the present application. Therefore, the Examiner is correct in that two of the inventors on the present application are also inventors on the Pack *et al.* reference. Given the overlap in inventive entities, the Pack *et al.* reference was not invented by another, and therefore, the Pack *et al.* reference cannot be used as prior art against the present application under 35 U.S.C. §102(e).<sup>1</sup>

A case directly on point *In re DeBaun*<sup>2</sup> has been included for the Examiner's review. In *DeBaun*, an issued patent by DeBaun and Doll was cited against a pending application by DeBaun in a § 103 rejection. DeBaun had submitted in the case a Declaration stating that the claimed invention in the application was invented solely by him, but the examiner maintained the rejection and the board sustained the rejection. The court, however, reversed the board stating that "an applicant's own work, even though publicly disclosed prior to his application, may not be used against him as a reference" citing *In re Katz*.<sup>3</sup> The court concluded by stating that "the '678 patent to appellant and Noll, having issued less than one year before the filing date of appellant's original '519 patent application, is only available as a reference if the pertinent disclosure is not the sole work of the appellant" and goes on to state that the declaration submitted by DeBaun was sufficient evidence to conclude that the claimed invention in the application was DeBaun's sole invention. The present application presents a similar situation. The now issued U.S. Patent 6,692,911 was invented by three persons, two of which are the inventors on the present application. A Declaration by Professor Langer has been submitted in this case as evidence that Pack was not an inventor on the claimed subject matter in the present application. Therefore, in light of the case law and the Declaration previously submitted, Applicant requests that the reference be removed since the material disclosed in the published patent was not invented by another and can not be used as prior art to render obvious the claimed

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<sup>1</sup> A person shall be entitled to a patent unless—(e) the invention was described in (1) an application for patent, published under section 122(b), *by another* in the United States before the invention by the applicant for patent . . . . 35 U.S.C. § 102(e) (2004).

<sup>2</sup> 687 F.2d 459 (C.C.P.A. 1982).

<sup>3</sup> 687 F.2d 450 (C.C.P.A. 1982).

invention in the present application.

In addition, Applicant submits that the Pack *et al.* reference does not qualify as prior art under 35 U.S.C. § 103 via 35 U.S.C. § 102(e) because the subject matter in Pack *et al.* and the claimed invention in the present application were, at the time the invention was made, owned by the same entity or were subject to an obligation of assignment to the same entity. Since the present application was filed on April 20, 2000 (after the effective date of November 29, 1999 of § 103(c)), the subject matter of Pack *et al.* does not constitute prior art under § 102(e) applicable under § 103. *See* MPEP § 706.02(l)(1). Both the subject matter of the Pack *et al.* reference and the claimed invention were subject to assignment to the Massachusetts Institute of Technology at the time the invention was made because the inventors of the patent and the present application were either employees, post-doctoral fellows, and/or students of the Massachusetts Institute of Technology. Therefore, Applicant requests that the Pack *et al.* reference be excluded from consideration by the Examiner under § 103.

Without Pack *et al.*, the *prima facie* case of obviousness has not been made because as the Examiner admits “Pack *et al.* teaches a cell delivery composition comprising a polymeric carrier, which comprises an endosomolytic polymer having ionizable functional moieties or monomers, and a biological active agent . . . .” Therefore, Applicant requests that the rejection be removed.

#### **IV. Rejection for Obviousness-type Double Patenting over co-pending application**

**USSN 09/251,783.** Claims 1-12, 14-32, 35, 39, 41, 42, and 44-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending patent application USSN 09/251,783 (the ‘783 application), now issued U.S. Patent 6,692, 911, taken with Thorpe (U.S. Patent 5,762,918). Applicant submits that the claims as allowed in the ‘783 application and the currently amended claims are patentably distinct. A copy of the U.S. Patent 6,692,911 (the ‘911 patent) that issued from the ‘783 application is included for the Examiner’s reference. The claims of the ‘911 patent include claims to biocompatible compositions that include a delivery agent, a nucleic acid, and an imidazole-containing endosomal agent and methods of using such a composition to lyse cells, whereas the claimed invention of the present application recites endosomal lysing polymers,



composition including endosomal lysing polymers, and methods of use thereof. Therefore, given the many differences between the issued claims in the '911 patent and the present application, Applicant submits that the claimed invention is not obvious in light of the '911 patent, even if taken with Thorpe.

However, to expedite allowance of this application, Applicant submits herewith a terminal disclaimer. The terminal disclaimer disclaims any portion of the term of a patent that issues from the present application that extends beyond the term of U.S. Patent 6,692,911. Applicant submits that the terminal disclaimer submitted herewith removes any basis for an obviousness-type double patenting rejection based on the '911 patent.

In view of the remarks provided above, Applicants respectfully request that the provisional, nonstatutory obviousness-type double patenting rejection be withdrawn and that the claims be allowed.

If it is believed that a telephone conversation would expedite matters, the Examiner is invited to contact the undersigned at (617) 248-5215. Although it is believed that there is no fee associated with this amendment, if Applicant is mistaken, please charge any fees to our Deposit Account Number: 03-1721.

Respectfully Submitted,

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